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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/052,889 | 01/18/2002 | Emil A. Tanagho | 02307E-080710US | 3329 |
| 20350 | 7590 | 03/06/2006 | EXAMINER | |
| TOWNSEND AND TOWNSEND AND CREW, LLP TWO EMBARCADERO CENTER EIGHTH FLOOR SAN FRANCISCO, CA 94111-3834 | | | PREBILIC, PAUL B | |
| | | ART UNIT | PAPER NUMBER | |
| | | 3738 | | |

DATE MAILED: 03/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/052,889 | TANAGHO ET AL. | |
| | Examiner | Art Unit | |
| | Paul B. Prebilic | 3738 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 22 December 2005.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 24-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 24-28 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____.

Election/Restrictions

Applicant elected Group III, claim 24 for prosecution on December 11, 2003.

Because of the amendment filed along with the election, no claims are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention because the only remaining claims are drawn to the elected invention.

Election was made **without** traverse in Paper No. 5 filed December 11, 2003.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 24-28 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3, 4, 8, and 10 of U.S. Patent No. 6,371,992. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present claims are so similar that they are considered obvious over each other. This is due to the fact that the bladder (patented claims) and the ureter or urethra as presently claim, are from the same tract

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and connected to each other. For this reason, it would have been obvious to make a matrix from one or the other because of their similarity in structure and function.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 24-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bishopric et al (US 5,855,620) or Goldstein (US 5,632,778) in view of Gregory (US 5,990,379). Bishopric (see column 3, lines 45-68) or Goldstein (see column 3, lines 11-20 and column 5, line 10 to column 6, line 52) each discloses producing intact collagen and elastin matrixes but not of ureter or urethra tissue as claimed. However, Gregory teaches that it was known to make intact elastin matrixes out of ureters; see column 4, lines 16-39 and column 5, lines 36-55. Therefore, it is the Examiner's position that it would have been obvious to make ureter tissue matrixes in the Bishopric or Goldstein inventions so that the particular tissue could be replaced in a recipient who needs such.

Regarding claims 26-28, the claimed properties would inherently be present because the primary references as modified by Gregory produce the same material as that claimed.

Response to Arguments

With regard to the double patenting rejection, Applicants have decided to withhold filing a terminal disclaimer until the claims are otherwise allowable. For this reason, the rejection has been maintained.

Applicants argued that the 37 CFR 1.131 declaration filed May 5, 2005 to overcome the Section 103 Abraham rejection, but this was considered insufficient. However, the 37 CFR 1.132 declaration (Katz declaration) filed July 27, 2004 was considered sufficient to overcome the rejection relying on Abraham. This is due to the fact that ureter/urethra tissues are considered to be obvious over bladder tissue since bladder tissue is from the same tract. Furthermore, this position is more consistent with the position taken in the double patenting rejection and in the prior art rejections of record; see MPEP 715.02 and 716.10 that are incorporated herein by reference thereto. In particular, the differences between the claimed invention and that of the Probst article are so small so as to render the claims obvious over the Probst article disclosure; see the first paragraph of MPEP 715.02. For this reason, the declaration is sufficient to overcome the rejection relying on Abraham by establishing an earlier date of invention.

In traversing the 35 USC 103 rejection, the Applicants argue that there is no motivation to combine Gregory with the primary references. In response, the Examiner asserts that the motivation to combine Gregory with the primary references is clearly provided in the rejection as "so that the particular tissue could be replaced in a recipient who needs such." Furthermore, since the references clearly come from the same field of endeavor, one would clearly look to other prior art of this field in order to determine

where there is a need and use for the invention. Since Gregory teaches that there is a need and use for the tissue treatment methods of the primary references in making ureter tissue grafts, the Examiner asserts that Gregory clearly provides the motivation to modify the primary references.

Applicants argue that there is no reasonable expectation of success in modifying the primary references because of the differences in properties between the urethra/ureter tissues and that of other tissues. However, the Applicants fail to point out and demonstrate the differences so this argument is considered to be a mere allegation. For this reason, it is not considered persuasive.

Applicants also argue that Gregory is not combinable with the primary references because it has a different process. However, Gregory was not combined with the primary references to point out the use of a different process. As pointed out previously in the record, one cannot show unobviousness by attacking references individually when the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

With regard to the 37 CFR 1.132 declaration filed December 22, 2005, the Examiner considered it insufficient to overcome the Section 103 rejection for the following reasons:

(a). The declaration appears to primarily an opinion of one of the inventors, Dr. Emil A Tanagho. In particular, no actual data is provided to compare the claimed invention against the closest prior art of record. Rather, the declaration states that the

primary references "simply cannot be expected to achieve the exceptional properties of the matrix graft of the present invention" (see paragraph 18, lines 1-3 thereof, of the declaration filed December 22, 2005). Since no comparative data was provided, it is not clear that the results of the primary references would be markedly different.

(b). The declaration asserts that there are unexpected results based upon the use in one human subject, but it does not point out how the results are unexpected (see paragraph 17 on page 6 of the declaration). Due to the fact that the declaration only provides evidence of success for one patient, it is almost about as valuable as anecdotal evidence. It is not clear that the result could be repeated with other patients.

(c). No actual quantitative experimental data was provided; only qualitative data was provided for one patient, and this data was not compared against data of tests done on tissues of the closest prior art. For this reason, the Examiner concluded that the declaration was primarily a statement of one inventor's opinion. It failed to provide objective proof of the alleged difference between the claimed invention and the prior art.

Conclusion

THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 or 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action if the application is not stored in image format (i.e. the IFW system) or published.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Paul B. Prebilic whose telephone number is (571) 272-4758. He can normally be reached on 6:30-5:00 M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, McDermott Corrine can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Paul Prebilic
Primary Examiner
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